APPEAL BRIEF EXAMINING GROUP 3738 Patent Application Docket No. GJE-7134 Serial No. 10/633,209

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner

William H. Matthews

Art Unit

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Applicant

Peter Toop

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For

Intraocular Lens

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APPEAL BRIEF

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February -1, 2000

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I. REAL PARTY IN INTEREST

The real party in interest is Rayner Intraocular Lenses Ltd., the assignee of record, located at Lowndes House, The Bury, Church Street, Chesham Bucks, HP5 1DJ in the United Kingdom.

II. RELATED APPEALS AND INTERFERENCES

Appellants are unaware of any related appeals or interferences.

III. STATUS OF CLAIMS

Claims 1-8 were finally rejected in the Office Action of August 31, 2007 under 35 U.S.C. §103(a). Claim 6 was also finally rejected under 35 U.S.C. §112, second paragraph. Claim 8 was also finally rejected under 35 U.S.C. §101. Claims 6 and 8 were cancelled by Amendment dated November 30, 2007. The rejections of claims 1-5 and 7 are appealed herein.

IV. STATUS OF AMENDMENTS

The Amendment of November 30, 2007, cancelling claims 6 and 8, has been entered by the Examiner, according to the Advisory Action dated January 11, 2008.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The independent claim involved in this appeal is claim 1. Claim 1 is directed to an intraocular lens comprising a toric optic and one or more haptics (page 1, lines 30-31; page 2, line 11 and lines 27-29; Figures 1A and 1B). Each haptic has a proximal part and a distal part (page 2, lines 5-6; page 2, line 31 through page 3, line 2; Figures 1A and 1B). The thickness of a region of the, or each, haptic is greater than the rest of the haptic, such that rotation of the lens is inhibited in use (page 1, line 31 through page 2, line 1; page 3, lines 2-11 and lines 27-32; Figures 1A-1C and 2)

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 1-5 and 7 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Toop (European Patent No. EP0962196, hereinafter "Toop") in view of Blake (U.S. Patent No. 6,425,917, hereinafter "Blake").

VII. ARGUMENT

A. Claims 1-5 and 7 are patentable because the Examiner has not set forth a proper basis for the combination of Toop and Blake in order to support a *prima facie* case of obviousness.

Claims 1-5 and 7 have been finally rejected under 35 U.S.C. §103(a) as being unpatentable over Toop (European Patent No. EP0962196, hereinafter "Toop") in view of Blake (U.S. Patent No. 6,425,917, hereinafter "Blake"). The appealed claims 1-5 and 7 stand or fall together for purposes of this Appeal.

The applicant respectfully submits that a *prima facie* case of obviousness has not been set forth because there is no reason for a skilled artisan to combine Toop and Blake in the manner suggested by the Examiner.

Establishing a *prima facie* case of obviousness requires a showing that "there was an apparent reason to combine the known elements in the fashion claimed" by the applicant. *KSR International Co. v. Teleflex Inc.*, 550 U.S. ____, 127 S.Ct. 1727 (2007); MPEP §2142. Additionally, "there must be some reason for the combination other than the hindsight gleaned from the invention itself." *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143 (Fed.Cir.1985).

Toop describes an intraocular lens for placement in the <u>capsular sac</u> in the posterior chamber of the eye (see, for example, paragraphs [0001], [0002], and [0015] – [0017] of Toop). Such a lens can exhibit the problem that, as the capsular sac contracts, the haptics of the intraocular lens can buckle and twist (paragraph [0002]). Toop seeks to solve this problem by teaching a lens that is resistant to haptic failure, by virtue of the fact that the haptics undergo a two-stage compression in the plane of the lens (paragraphs [0003] and [0004]).

Blake, on the other hand, discloses an intraocular lens of a completely different type. The Blake lens is an angle-fixated intraocular lens for placement in the <u>anterior chamber angle</u>, which is the junction between the iris and the cornea (column 2, lines 49-52; col. 3, lines 51-55; col. 4, lines 55-56). The diameter formed by the anterior chamber angle varies in the population, thus making sizing of angle-fixated intraocular lenses difficult. Blake addresses this problem by

having a two-part haptic, comprising two rigid elements bridged by a flexible, low modulus material (col2, lines 42-49). This functions to essentially hinge the haptic, allowing it to rotate and fit securely into the anterior chamber angle.

In Blake, the low modulus material (usually an elastomer) may extend towards the tip of the haptic, in order to provide a soft atraumatic contact point for the soft eye tissue. This can possibly have the incidental effect of making the distal part of the haptic thicker. However, no advantage or suggestion of desirability is given by Blake for having a thicker distal part of the haptic.

The present invention solves a problem that is different from both Toop and Blake; toric intraocular lenses are rotationally asymmetric and therefore must not rotate when positioned in the eye. Presented with the problem faced by toric intraocular lenses of needing to inhibit rotation, and starting with the teachings of the capsular intraocular lens in Toop, a skilled artisan would simply have no motivation or reason to turn to a publication describing angle-fixated intraocular lenses. The two areas of the eye have completely different anatomy, and a lens would presumably have to be modified if it were to be adapted for a different area of the eye.

Moreover, Blake does not even address the problem faced by toric intraocular lenses of needing to inhibit rotation. It should be noted that the skilled artisan would recognize that there is a clear distinction between the need to <u>inhibit rotation</u> and the need to "stabilize" the lens (i.e., reduce outward movement within the plane of the lens), which is a feature needed by all intraocular lenses. In fact, Blake only mentions a toric lens once, as one type in a long line of possible optics that can be used (col. 5, lines 55-57).

It has been well established in the patent law that the mere fact that the purported prior art could have been modified or applied in some manner to yield an applicant's invention does not make the modification or application obvious unless "there was an apparent reason to combine the known elements in the fashion claimed" by the applicant. This long-standing principle was recently re-affirmed by the U.S. Supreme Court. KSR International Co. v. Teleflex Inc., supra. Furthermore, an applicant's invention is not "proved obvious merely by demonstrating that each of its elements was, independently, known in the (purported) prior art." Id. As the foregoing remarks demonstrate, a skilled artisan would have found no reason to combine the teachings of Toop and Blake to arrive at the current invention.

Furthermore, in order to establish a *prima facie* case of obviousness, the Examiner must show that a skilled artisan would have had a "reasonable expectation of success." *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986); MPEP §2143.03. Also, the reasonable expectation of success must be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Here, even if one of ordinary skill in the art would have come across the Blake reference, he or she still would have had no reason to believe that rotation of an intraocular lens would be inhibited by making a haptic thicker in the distal region. As discussed above, the fact that a haptic appears to possibly be thicker in the distal region in Figures 3A-3B of Blake is an incidental effect, and there is no disclosure in Blake of any advantage that might be gained by such a feature.

Moreover, a skilled artisan would recognize that, if the intraocular lens of Blake were to be placed in the capsular sac, the contractions of the capsular sac would cause haptic failure of the Blake lens, leading to twisting and buckling of the haptics. As discussed above, the Toop lens is specifically designed for use in the capsular sac. Thus, once again, one of ordinary skill in the art would not have found a reasonable expectation of success in combining the Blake and Toop references.

The Examiner argued that it would have been obvious to modify the intraocular lens of Toop to include a toric optic and thicker distal parts in order to treat patients in need of a toric optic and provide a better stabilized and atraumatic lens upon implantation. However, a skilled artisan would have had no reason to even seek out Blake to combine with Toop in the first place, since they are directed to lenses for different parts of the eye. Additionally, there is no mention in Blake of any advantage that might be gained by haptics with thicker distal parts. Thus, a skilled artisan would not have found any reason to use thicker distal parts on each haptic to provide a better stabilized lens as the Examiner has asserted.

The applicant respectfully submits that, in this case, a reason to combine the cited references may be found only with resort to the hindsight provided by the applicant's own disclosure. It is impermissible to use the claimed invention as an instruction manual or "template" to piece together the teachings of the prior art so that the claimed invention is rendered obvious. The Court of Appeals for the Federal Circuit has stated that "[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." *In re Fritch*, 23 U.S.P.Q.2d 1780, 1784 (Fed. Cir. 1992).

As discussed above, there would have been no reason for a skilled artisan to combine Toop and Blake to arrive at the claimed invention. Additionally, a skilled artisan would have found no reasonable expectation of success in combining the cited references. Because the combination of references set forth by the Examiner lacks the requisite reason to combine and reasonable expectation of success, the combination cannot support a *prima facie* case of obviousness. "If the examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness." MPEP §2142.

Accordingly, the applicant respectfully requests reversal of the Examiner's rejections of claims 1-5 and 7.

B. Conclusion

In view of the foregoing, the appellants urge the Board to reverse the outstanding rejections under 35 U.S.C. §103(a) and pass this application to issuance.

Respectfully submitted,

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VIII. CLAIMS APPENDIX

- 1. An intraocular lens comprising a toric optic and one or more haptics, each haptic having a proximal part and a distal part, wherein the thickness of a region of the distal part of the, or each, haptic is greater than the rest of the haptic, such that rotation of the lens is inhibited in use.
- 2. The lens according to claim 1, wherein the thickness of the, or each, haptic is greatest at the periphery.
- 3. The lens according to claim 1, wherein the, or each, haptic is compressible, in the plane of the lens.
- 4. The lens according to claim 3, wherein the, or each, haptic is curved, and shaped such that, in a first stage of compression, the proximal part of the haptic can be fully compressed and, in a second stage, the distal part of the haptic can be compressed.
- 5. The lens according to claim 4, wherein the, or each, haptic includes an aperture of which opposed points are brought into contact, in the first stage of compression.

Claim 6 was cancelled by Amendment dated November 30, 2007.

7. The lens according to claim 4, which comprises two haptics, wherein the haptics are compressed to provide an essentially elliptical form of the lens.

Claim 8 was cancelled by Amendment dated November 30, 2007.

IX. EVIDENCE APPENDIX

None.

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X. RELATED PROCEEDINGS APPENDIX

None.